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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/715,909	11/17/2000	Ronald D. Flannagan	35718/204664	5613

29122 7590 07/15/2005

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EXAMINER

HAYES, ROBERT CLINTON

ART UNIT PAPER NUMBER

1649

DATE MAILED: 07/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/715,909

Applicant(s)

FLANNAGAN ET AL.

Examiner

Robert C. Hayes, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 7, 10-18, 28-32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7, 10-18, 28, 29, 32, 34, 35 and 37-39 is/are rejected.
- 7) ☒ Claim(s) 30, 31 and 36 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The amendment filed 4/28/05 has been entered.
2. Applicants' arguments filed 4/28/05 have been considered but were not found persuasive.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
4. Claims 30-31 & 36 stand objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
5. Claims 1-3, 7, 10-18, 28-29, 32, 34-35 & 37-39 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed, for the reason made of record in Paper NOs: 10 (mailed 2/13/02), 13 (mailed 10/18/02), 16 (mailed 4/07/03), 21 (mailed 11/17/03), 2040506 & 20050127, and as follows.

Applicants re-iterate their previous arguments on pages 7-10 of the response. In contrast to Applicants' assertions, no correlation between any structural domains and the recited

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functional characteristics have been described in the specification to “couple... a known or disclosed correlation between function and structure, or some combination of these disclosed characteristics” (i.e., as it relates to the claimed genus). For example, all of the claims are not even correlated to the single disclosed full length nucleic acid of SEQ ID NO: 1, which is the only sequence disclosed that encodes any functional polypeptide (e.g., as it relates to claim 1 f). Therefore, the issue is clear. The single disclosed species of an *Ostrinia nubilalis* receptor nucleic acid molecule of SEQ ID NO: 1 is not reasonably representative of the *Lepidopteran* order/genus claimed; thereby, not reasonably providing written description of the claimed genus. As extensively made of record, the specification fails to describe a single other nucleic acid molecule by a known and recognizable structure that reasonably would be representative of any different insect species within the *Lepidopteran* order, or even within the *Pyraloidea* superfamily; especially as it relates to any reasonable correlation of structure with function within the claimed genus. A single disclosed species does not represent a genus without a “known or disclosed correlation between function and structure, or some combination of these disclosed characteristics”, which usually is derived from a structure/function correlative study derived from a representative number of species within a given genus/order/superfamily. In contrast, no “genus of nucleic acid molecules” have been disclosed within the specification. In fact, not a single other insect nucleic acid molecule to putatively establish a representative number of species within the claimed genus has been described within the instant specification. Thus, in contrast to Applicants’ assertions, the pending rejection is consistent with the current Guidelines, and that held by the court in *Enzo*, and in *Fiers v. Revel* and *Univ. California v. Eli Lilly and Co.* previously made of record. Thus, Applicants are clearly not in possession of the

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claimed genus of *Lepidopteran* insect receptor nucleic acid molecules claimed, for the reasons made of record.

It is noted that Applicants have ignored the suggestion of the Examiner to overcome rejection of some of the claims dependent directly or indirectly on claim 1a, e & g by amending claim 1 to “a nucleotide sequence encoding [a *Lepidopteran*] *Ostrinia nubilalis* insect receptor polypeptide...”, because the nucleic acid molecule of SEQ ID NO: 1 may be argued to be representative of allelic variants within the disclosed insect species, *Ostrinia nubilalis*, with the recited functional language and the disclosed correlation between the structure of SEQ ID NO: 1, in this one population of insects, which possess unique characteristics that distinguish themselves from any other insect species, etc.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (571) 272-0885. The examiner can normally be reached on Monday through Thursday, and alternate Fridays, from 8:30 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet Andres, can be reached on (571) 272-0867. The fax phone number for this Group is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Robert C. Hayes, Ph.D.
July 12, 2005

ROBERT C. HAYES, PH.D.

Primary **PATENT EXAMINER**